REMARKS

Summary of Amendments to the Claims

By the present amendment, claim 1 is amended, claim 4-8 are canceled, whereby claims 1-3 and 9 are currently pending.

Claim 1 is amended to clarify the claim as suggested by the Examiner. Applicants note that support for the amendments to claim 1 can be found throughout the specification, and is inherent therein.

Claims 4-8 are canceled to advance prosecution of the application, and are not dedicated to the public. Applicants reserve the right to file continuation and/or divisional applications including any canceled subject matter.

Applicants submit that no new matter is added.

Summary of Communications with Examiner – In Person Interview of 4/1/2009

Applicants thank Examiners Valerie Lubin and Christopher Gilligan for the courtesies extended during the in person interview with Applicants' Representative Wesley Nicolas (Reg. No. 56,129) on April 1, 2009.

Applicants note that the Interview Summary mailed from the USPTO April 13, 2009 is complete and no further clarification is necessary.

Foreign Priority Documents

The Office Action Summary indicates that "None of:" the certified copies of the priority documents have been received.

In response, Applicants note that the present application is a Continuation application of U.S. Patent Application No. 09/462,128. In this regard, the appropriate foreign priority documents were filed in U.S. Patent Application No. 09/462,128 (the "parent" application), and thus Applicants need not submit the foreign priority documents again to the USPTO (as provided for by MPEP § 201.14(b)).

Supplemental Information Disclosure Statement

Applicants thank the Examiner for consideration of the Information Disclosure Statement filed October 10, 2003, by returning an initialed copy of the Form PTO-1449 submitted therein.

Applicants submit concurrently herewith, and listing in a First Supplemental Information Disclosure Statement, U.S. Patent No. 6,544,212 (which is not prior art to the present application), and all patents/publications listed on the face of U.S. Patent No. 6,544,212.

Accordingly, Applicants request that the Examiner review and initial the Form PTO-1449 submitted with the Supplemental Information Disclosure Statement, in the next communication from the Office.

Response to Rejection under 35 U.S.C. § 112, Second Paragraph

The Office Action rejects claims 1-9 under 35 U.S.C. 112, Second Paragraph because it alleges that at least claim 1 is unclear because it recites a method step but is directed to a system.

In response, Applicants amend claim 1 to further clarify the claim to show that the master module is configured to do the specified tasks (e.g., transmit the predicted dose of insulin to the insulin delivery unit). Regarding claim 9, Applicants respectfully submit claim 9 is clear for at least the same reasons as claim 1. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, Second Paragraph.

Response to Art Rejections – 35 U.S.C. § 103

Turning to the rejections under 35 U.S.C. § 103(a), Applicants have considered the 35 U.S.C. § 103 rejections in the Office Action, but disagree that claims 1-6 and 9 are obvious over Castellano et al. (U.S. Patent No. 5,536,249, "CASTELLANO") alone; or that claims 7-8 are obvious over CASTELLANO, and further in view of Worthington et al. (U.S. Patent No. 5,822,715, "WORTHINGTON").

In particular, Applicants respectfully note that at least claims 7-8 are cancelled by the present amendment to advance prosecution, therefore the only document relevant in the standing rejection(s) is CASTELLANO. For at least the reasons explained below, CASTELLANO fails to disclose all elements of Applicants' invention, and likewise the Office Action does not present a sustainable *prima facie* case of obviousness.

The Office Action at page 3 submits that:

> Castellano does not specifically recite transmitting the does of insulin to the insulin delivery unit; however, he does disclose an I/O port capable of receiving and transmitting (Col. 14 lines 42-49). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of Castellano to not only receive data from the insulin delivery unit, but also to transmit data back to it in order to facilitate and expedite data flow.

In response, Applicants respectfully submit that while CASTELLANO may disclose an I/O port, it stops short of disclosing or suggesting at least "*a master module ...configured to ... transmit the predicted dose of insulin to the insulin delivery unit*" as in claim 1. Likewise, CASTELLANO does not disclose or suggest at least "*a communication unit that transmits the corrective amount to the delivery unit*" as in claim 9. Therefore, in stark contrast to Applicants' claimed invention, the I/O port in CASTELLANO does nothing more than transmit data in or out of the device, and thus does not "*transmit the predicted dose of insulin to the insulin delivery unit*" as in claim 1, or "*transmit[] the corrective amount to the delivery unit*" as in claim 9.

In view of at least the foregoing arguments, CASTELLANO fails to disclose or suggest all elements of the rejected claims. Therefore, Applicants respectfully request that all rejections under 35 U.S.C. § 103(a) be withdrawn.

Suggested Interference with U.S. Patent No. 6,544,212

Further to MPEP §§ 2304.02(c), 2304.04(a) and 37 CFR § 41.202, Applicants suggest and present claims 1 and 9 in this application for the purposes of provoking an interference with US Patent No. 6,544,212, a copy of U.S. Patent No. 6,544,212 is submitted herewith (in a Supplemental IDS). Specifically, Applicants suggest **Count 1** as Applicants claim 1 which is substantially the same as claim 1 of U.S. Patent No. 6,544,212. Alternatively, Applicants suggest **Count 2** as Applicants claim 9, which is copied as claim 1 of U.S. Patent No. 6,544,212. Accordingly, Applicants suggest **Count 1** and/or **Count 2** as suggested interference counts.

Applicants note that the requirements of 35 U.S.C. § 135(b)(1) are met because claims 1 and 9 in the present application were pending at least as early as September 17, 2003, less than one year after the issuance of U.S. Patent No. 6,544,212 (*i.e.*, issued April 8, 2003). Likewise,

the requirements of 35 U.S.C. § 135(b)(2) are met because claims 1 and 9 in the present application were pending at least as early as September 17, 2003, less than one year after the publication of U.S. Patent Application Publication No. 2003/0028089 (*i.e.*, published February 6, 2003), the publication corresponding to U.S. Patent No. 6,544,212.

Applicants claims 1 and/or 9 would prevail in priority of at least claim 1 of U.S. Patent No. 6,544,202 because Applicants claim priority of at least one of 35 U.S.C. §§ 119, 120, 121, and 365 by over 2 years 8 months as compared to U.S. Patent No. 6,544,212.

Pursuant to 37 C.F.R. §§ 41.202(a)(3) and 41.203(a), Applicants provide on the following pages claim charts for each proposed Count showing why at least claim 1 of U.S. Patent No. 6,544,212 interfere with claims 1 and 9 of the present application. The bolded text in the table below demonstrates clearly that that the patent claim corresponds to the alternative proposed count, as it is indisputable that the bolded text in each column has the same scope.

Suggested Interference Count 1:

Applicants' claim 1	US 6,544,212 claim 1
1. A system **for assisting a diabetic subject in controlling blood glucose** levels, the system comprising:	1. A system for providing **glycemic control** to a subject, the system comprising:
a. an **insulin delivery** unit;	an **insulin delivery** unit,
b. a **blood glucose monitor**;	a glucose sensor,
c. a **master module** that	a **control unit** including
includes a **processor** that is **configured to receive a blood glucose** value	a **processor** unit **that receives glucose value** readings
from the **blood glucose monitor** and	from the **glucose sensor**,
to **run a model that predicts a future glucose value** and	**executes an algorithm that predicts a glucose value** at a pre-determined time in the future,
compares that value with a target value and	**compares that predicted glucose value to a pre-determined glucose value range**, and
then predict a dose of insulin that will result in an acceptable blood glucose level	**determines a corrective amount of insulin to be administered** when the predictive glucose value lies outside of the pre-determined glucose value range and
and **transmit the predicted dose of insulin to the insulin delivery unit**.	**communicates the corrective amount to the delivery unit**.

Suggested Interference Count 2:

Applicants' claim 9	US 6,544,212 - Claim 1
9. A system for providing **glycemic control** to a subject, the system comprising: an **insulin delivery** unit, a glucose sensor, a **control unit** including a **processor** unit **that receives glucose value** readings from the **glucose sensor**, **executes an algorithm that predicts a glucose value** at a pre-determined time in the future, **compares that predicted glucose value to a pre-determined glucose value range**, and **determines a corrective amount of insulin to be administered** when the predictive glucose value lies outside of the pre-determined glucose value range and **communicates the corrective amount to the delivery unit**.	1. A system for providing **glycemic control** to a subject, the system comprising: an **insulin delivery** unit, a glucose sensor, a **control unit** including a **processor** unit **that receives glucose value** readings from the **glucose sensor**, **executes an algorithm that predicts a glucose value** at a pre-determined time in the future, **compares that predicted glucose value to a pre-determined glucose value range**, and **determines a corrective amount of insulin to be administered** when the predictive glucose value lies outside of the pre-determined glucose value range and **communicates the corrective amount to the delivery unit**.

In addition, pursuant to 37 C.F.R.§ 41.203(a), Applicants assert that at least claims 1 and 9 of the present application would, if prior art, have anticipated or rendered obvious at least claim 1 of U.S. Patent No. 6,544,212 in view of suggested Count 1 and/or Count 2 and therefore they should all be designated as corresponding to the Count(s).

Support for the claims 1-3 and 9 can be found in the specification. The claims are reproduced below with bold/bracketed text that indicates examples of where support for each element can be found in the specification:

1. A system for assisting a diabetic subject in controlling blood glucose levels, the system comprising:

a. insulin delivery unit **[*see* p. 9, lines 10, 18; Figure 5]**;

b. blood glucose monitor **[*see* p. 9, lines 8-12; p 20, lines 4-9; Figures 5-6]**;

c. a master module **[p. 28 line 14]** that includes a processor that is configured to receive a blood glucose value from the blood glucose monitor **[*see* p 20, lines 4-9]** and to run a model that predicts a future glucose value **[p. 13, lines 21-27]** and compares that value with a target value and then predict a dose of insulin that will result in an acceptable blood glucose level **[p 13, line 29- p. 14 line 2; see also p. 21, lines 4-14]** and transmit the predicted dose of insulin to the insulin delivery unit **[*see* p. 21 lines 4-14].**

2. The system of claim 1, wherein the processor is configured to receive other data from the subject. **[p. 8, lines 6-30]**

3. The system of claim 2 wherein the data includes information on size and type of meal to be ingested and anticipated duration and intensity of exercise. **[p. 8, lines 8-13].**

9. A system for providing glycemic control to a subject, the system comprising:

an insulin delivery unit **[*see* p. 9, lines 10, 18; Figure 5]**,

a glucose sensor **[*see* p. 9, lines 8-12; p 20, lines 4-9, Figures 5&6]**,

a control unit **[p. 28 line 14]** including a processor unit that receives glucose value readings **[*see* p 20, lines 4-9]** from the glucose sensor, executes an algorithm **[p. 13, lines 21-27]** that predicts a glucose value at a pre-determined time in the future, compares that predicted glucose value to a pre-determined glucose value range, and determines a corrective amount of insulin to be administered when the predictive glucose value lies outside of the pre-determined glucose value range **[p 13, line 29- p. 14 line 2; see also p. 21, lines 4-14]** and a communications unit that transmits the corrective amount to the delivery unit **[*see* p. 21, lines 4-14]** .

Conclusion

In conclusion, Applicants respectfully submit that the documents asserted in the Office Action do not disclose or suggest every element of Applicants' claims. Moreover, for at least the reasons set forth above, Applicants respectfully assert that the present Application interferes with US Patent No. 6,544,212 and request that an interference be declared. Applicants suggest that claim 9 and/or claim 1 serve as the basis for the Count or Counts.

The Commissioner is hereby authorized to charge any fees, including fees for extensions of time, in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. Should the Examiner have any questions or concerns, she should feel free to contact the applicants' attorney to discuss them.

Respectfully submitted,

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